

# **EXHIBIT 5**

## Minimal Incision Surgery as a Risk Factor for Early Failure of Total Knee Arthroplasty

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**Abstract:** A consecutive series of revision total knee arthroplasty (TKA) performed at 3 centers by 5 surgeons for a 3-year period was reviewed. Revisions performed for infection and rerevisions were excluded. Review of clinical and radiographic data determined incision type, sex, age, time to revision, and primary diagnosis at time of revision. Two-hundred thirty-seven first-time revision TKAs were performed, of which 44 (18.6%) had been a minimal incision surgery (MIS) primary TKA and 193 (81.4%) had been a standard primary TKA. Patients with MIS were younger (62.1 vs 66.2 years,  $P = .02$ ). Most striking was the difference in time to revision, which was significantly shorter for the MIS group (14.8 vs 80 months,  $P < .001$ ). Minimal incision surgery TKA accounted for a substantial percentage of revision TKA in recent years at these centers. The high prevalence of MIS failures occurring within 24 months is disturbing and warrants further investigation. **Key words:** MIS, total knee arthroplasty, revision, early failure.

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The standard surgical approach for total knee arthroplasty (TKA) has traditionally involved a

relatively long midline incision, a medial parapatellar arthrotomy, patellar eversion, and tibiofemoral dislocation as described by, (although did not originate from) Lotke [1]. Although this surgical approach is more extensive, it allows for excellent visualization, component orientation, fixation, and has been associated with remarkable long-term implant survival [2-4]. In the 1990s, Repicci [5] described an approach for implanting unicondylar components with smaller specialized instruments, a much shorter skin incision, limited, if any, incision into the quadriceps tendon, and avoidance of patellar eversion or tibiofemoral dislocation. The midterm results using this technique appeared promising [6]. Incorporation of these concepts into subsequent unicondylar knee arthroplasty (UKA) systems lead to a tremendous resurgence in interest and use of UKA [7].

Although excellent long-term implant survival has undoubtedly been demonstrated for TKA, patient-centered outcome studies in the 1990s showed that there was room for improvement in the clinical results of TKA from the patient's perspective. Trousdale et al [8] showed that the

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Each author certifies that his institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

Level of evidence: level 3, case control study and systematic review.

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2 greatest concerns regarding joint arthroplasty were pain control and length of recovery. Dickstein et al [9] showed that one third of elderly patients were dissatisfied at 6 and 12 months after knee arthroplasty. Noble et al [10] recently demonstrated significant residual functional difficulties after TKA. These studies indicated potential for improvement in the clinical results of TKA particularly in the areas of pain control, length of recovery, range of motion, and return to full function.

Numerous short-term results have now appeared in the peer review literature, and most claim a number of advantages of minimal incision surgery (MIS) over TKA through a standard incision including less blood loss [11-13], less perioperative pain and narcotic use [14], shorter length of stay [14-16], earlier return of function [16,17], earlier independent straight leg raise [18-20], higher level of patient satisfaction [21], ability to perform surgery on an outpatient basis [22], increased cost-effectiveness [23,24], less need for inpatient rehabilitation post-discharge [14], less need for assistive devices [14], a lower incidence of lateral release [25], and increased range of motion in the short term [17,20,26]. The major focus of most authors in supporting MIS overall has been the improved patient satisfaction, quicker recovery, and earlier discharge. Most of these studies, however, have been reported by designers and/or advocates of the techniques or systems that were the subject of the investigations. In addition, all were total knee specialists with extensive prior experience with standard TKA and were high-volume surgeons. Numerous studies have demonstrated higher complication rates after joint arthroplasty when performed by lower-volume surgeons or at lower-volume centers [27-29]. Most TKA procedures are performed by low-volume surgeons [28]; however, MIS TKA is now being promoted for widespread use and is being performed far beyond the limited group of surgeons who have published the early results of MIS TKA. There is very limited data available on the clinical results or complication rates of MIS TKA performed in the general orthopedic community. To examine this issue, we reviewed a series of revision TKAs at 3 referral centers performing revision surgery predominantly from area community surgeons. Revisions of MIS TKA were compared with TKA performed through a standard surgical approach.

## Materials and Methods

A consecutive series of revision TKA undertaken by 5 surgeons at 3 centers during a 3-year period

(2004-2006) was reviewed. During this interval, 341 revision procedures were performed. Revisions performed for infection or rerevisions were excluded, leaving a total of 237 cases for review. A detailed clinical analysis included review of clinic notes, prerevision and postrevision radiographs, and the operative report of the revision procedure. Data obtained on every patient included age, sex, body mass index (BMI), time to revision, primary diagnosis at revision, components revised, and incision type. Incisions whose proximal extent was at or within 1 cm of the superior pole of the patella and was less than 14 cm were classified as an MIS TKA as described by Bonutti et al [30] and Laskin [20]. This was confirmed with the original operative report or referring surgeon's records. The type of MIS approach (eg, Quad sparing) was not described consistently enough to record. All of the MIS procedures and more than 90% of the non-MIS primary TKAs were performed outside the institutions performing the revision procedure. Revisions of MIS were compared with non-MIS revisions. The data were analyzed and the descriptive statistics (means and ranges) were calculated with Microsoft Excel (Redmond, Wash). All other analyses were performed with the SPSS (Chicago, Ill) statistical software package. Continuous variables were analyzed with Student *t* test. Categorical data were compared with use of the  $\chi^2$  test or the Fisher exact test with the level of significance set at  $P \leq .05$ .

In addition, a structured review of the currently available literature on MIS TKA was undertaken. A search of PUBMED/Index Medicus was performed with the search terms *total knee* and *minimally invasive* and *surgery*. All English language articles that included clinical outcomes, complications, and revision rates were included for review. Eighteen clinical studies were identified and analyzed to determine the following: study type, duration of follow-up, number of knees studied, the incidence and type of complications, and the revision rate. Radiographic complications were defined as those not requiring reoperation or further treatment, but that might predispose to symptoms or early failure such as malalignment, patellar tilt, radiolucency, or component malposition. Radiographic complications were distinguished from clinical complications with both rates reported.

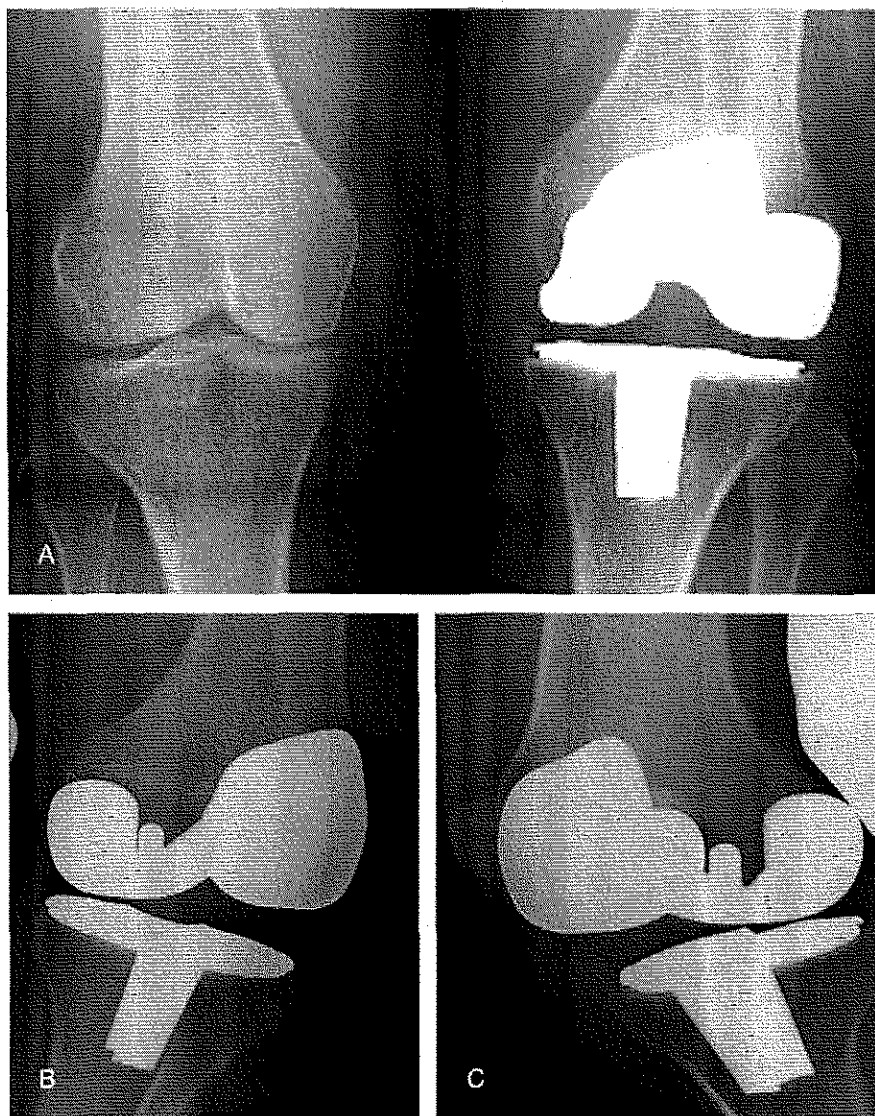
## Results

Of the 237 first-time revisions, 193 had originally been performed through a standard approach

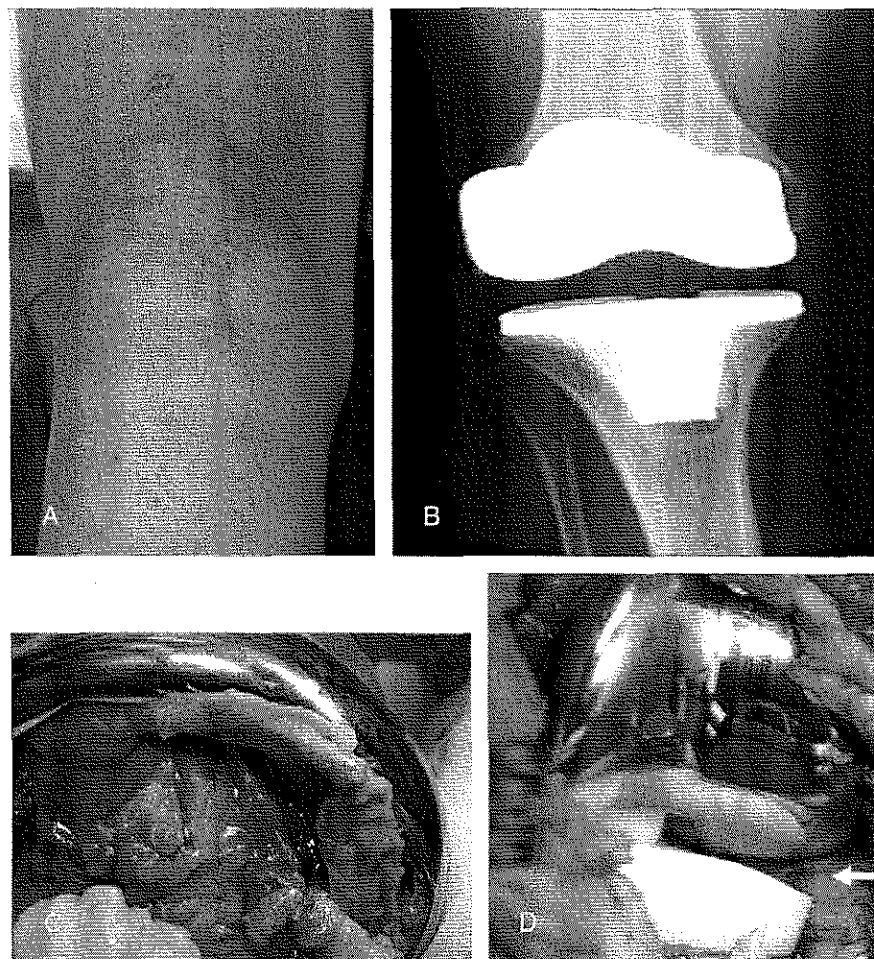
(81.4%) and 44 met the criteria for an MIS approach (18.6%). Patients who had had the MIS approach were significantly younger (62.1 vs 66.2,  $P = .02$ ). Patients with MIS TKA had a higher percentage of female patients, which showed a trend toward significance ( $P = .12$ ). There was no difference in BMI between MIS and non-MIS groups (31.4 vs 31.3). The most striking difference was the average time to revision for the patients with MIS, which was 14.8 vs 80 months ( $P < .001$ ). Patients who had originally had an MIS approach were much more likely to fail within 12 months ( $P < .001$ ) and as well as within 24 months ( $P < .001$ ). Minimal incision surgery knees were almost twice as likely to have malrotation or instability as

a cause of failure (38.6% vs 21.8%,  $P < .05$ ) (Fig. 1). Although loosening was more common in the MIS group, however (Fig. 2), this was not statistically significant ( $P = .12$ ). Patients in the MIS group were much less likely to have polyethylene wear or osteolysis as a primary cause of failure compared with the standard TKA group undoubtedly because of the short time in situ before revision for most MIS knees. There was also a trend for the non-MIS group to have more failures due to extensor mechanism problems (such as late patellar loosening fracture) (Table 1).

The structured literature review revealed 192 published studies of which only 18 described clinical outcomes including length of follow-up,



**Fig. 1.** Anteroposterior radiograph of left MIS total knee demonstrating acceptable alignment (A) but gross laxity to varus (B) and valgus (C) stress.



**Fig. 2.** (A), Clinical photograph showing a 10-cm medial incision of MIS TKA that loosened and was revised in less than a year. (B), Early postoperative anteroposterior radiograph demonstrating extensive tibial bone-cement radiolucency. The intraoperative photograph showed incomplete femoral seating laterally with retained cement (C) and medial instability (see arrow) (D).

number of knees followed, complications, and revisions. These 18 studies reported on a total of 1490 MIS total knees with an average follow-up of 17.2 months. Only 6 of these reports had follow-up averaging 24 months or greater. The

clinical complication rate reported was 52 (3.5%) of 1490, with an additional radiographic complication rate reported of 36 (2.5%) of 1490, which when combined, yields an overall complication rate of 5.9%. There were only a total of 12

**Table 1.** Comparison of Revisions of MIS vs Non-MIS TKA

	MIS (n = 44)	Non-MIS (n = 193)	P
Age (y)	62.1 (range, 38-80)	66.2 (range, 27-94)	.02
Sex (% female)	75% (33)	63% (121)	.12
Time to revision (mo)	15.4 (range, 5-36)	79.2 (range, 2-312)	<.0001
% Revised at <12 mo	39% (17)	7% (13)	<.0001
% Revised at 12-23 mo	43% (19)	18% (35)	<.0001
% Revised at >24 mo	18% (8)	74% (144)	<.0001
Primary reason for revision			
Loosening	59.1% (26)	50.8% (98)	.319
Malposition/instability	38.6% (17)	21.8% (42)	.019
Pain/stiffness	2.3% (1)	5.7% (11)	.349
Wear/lysis	0% (0)	16.6% (32)	.004
Patella/extensor Mechanism	0% (0)	5.2% (10)	.123

revisions reported for a short-term revision rate of 0.8% (Table 2).

### Discussion

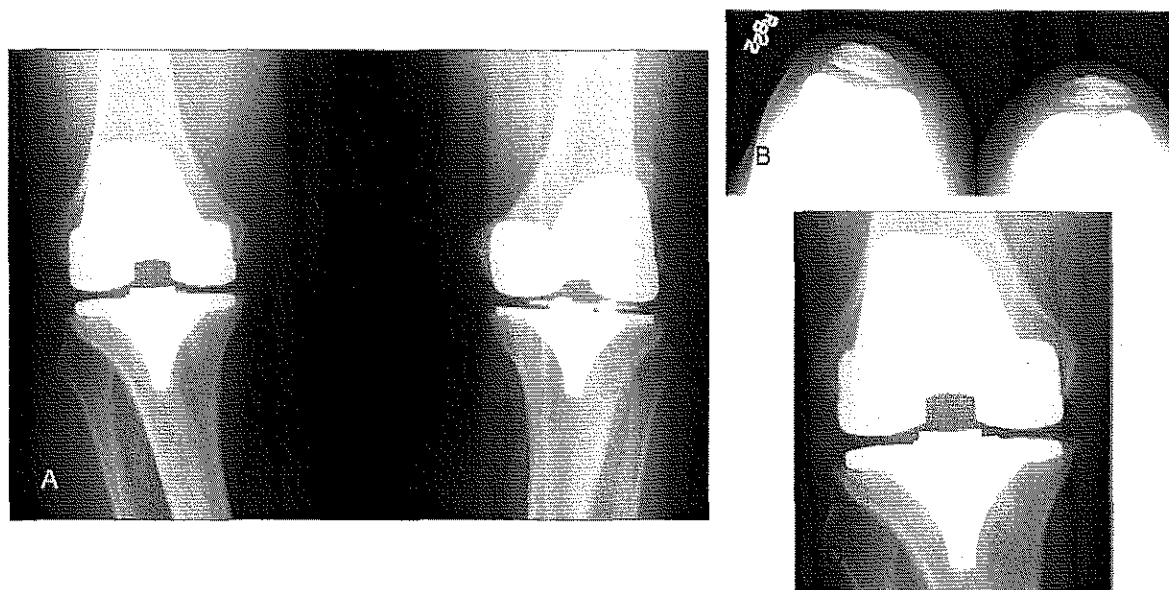
Although the short-term results of MIS TKA have been good in the hands of experienced surgeons, there has been cause for concern even in this setting. Serious complications have occurred early in the experience of leading surgeons, including vascular injury [11], patellar tendon injury [18,31], condyle fracture [18], and wound necrosis [15,32]. Similar to the experience of Fisher et al with UKA, Dalury

and Dennis [33] reported greater than 3° of tibial varus in 4 of 30 MIS TKAs and warned of the potential for compromise of long-term results with MIS TKA (Fig. 3). Substantial tibial varus has been shown to correlate with increased polyethylene wear and tibial component loosening [34]. Other studies have shown less consistent component alignment and longer operative times with MIS TKA compared with a standard approach [31-33,35-37]. A recent study by King et al [14] focused on the learning curve for MIS TKA and estimated it to be 25 cases for consistent patella preparation. This was in the hands of high-volume experienced total joint surgeons, which caused the authors to express

**Table 2.** Clinical Studies of MIS TKA Reporting Complications and Revision Rate

Author	Study Design	F/U (mo)	No. of Knees	Complications	Revision Rate
Chin et al [36]	RCT—radiographic outcomes	NA	60	Wound 1 (1.7%), stiffness 2 (3.3%), <b>malalignment—mechanical axis 12 (20%)</b>	0
Kolisek et al [15]	RCT	3	40	Wound 4 (10%)	0
King et al [14]	Retrospective cohort	105	100	Manipulation 1 (1%)	0
Tashiro et al [37]	Retrospective cohort	16	24	<b>Tibial component medial shift 4 (17%)</b> , wound healing 1 (4%)	0
Aglietti et al [31]	RCT	3	60	Retained cement 5 (8.3%), patellar tendon injury 1 (1.6%), <b>medialized tibial component 7 (12%)</b> , hemarthrosis 1 (1.6%)	0
Bonutti et al [51]	Retrospective cohort: AVN	24	15	0	0
Bonutti et al [52]	Retrospective cohort—revision TKA	29	17	Patellar maltracking 1 (6%), retained cement 1 (6%)	1 (6%)
Lombardi et al [53]	Retrospective cohort	9	97	0	0
Pagnano et al [32]	Prospective cohort	12	103	Delayed wound healing 2 (1.9%), <b>valgus mechanical axis 1 (1%)</b>	0
Berger et al [22]	Prospective cohort	3	50	Wound problems 4 (8.0%), arthrofibrosis 1 (2.0%)	2/50 (4.0%)
Boerger et al [18]	RCT	3	60	Lateral release 3 (5%), patellar tendon rupture 1 (1.7%), fracture lateral femoral condyle 1 (1.6%)	0
Dalury et al [33]	Retrospective cohort	3	30	<b>Malalignment 4 (13.3%)</b> , <b>patellar tilt 3 (10%)</b> , prolonged drainage requiring Abx 3 (10%)	0
Laskin [20]	Retrospective consecutive series	28	94	<b>Malalignment 1 (1.1%)</b> , <b>patellar tilt 2 (2.2%)</b> , <b>radiolucency 2 (2.2%)</b>	0
Tenholder et al [54]	Retrospective cohort	505	69	Superficial erythema 2 (2.9%), common peroneal n palsy 1 (1.4%), patellar dislocation 1 (1.4%)	1/69 (1.4%)
Bonutti et al [30]	Retrospective cohort	36	216	Closed manipulation 6 (2.8%), sepsis 2 (0.7%), tibial pain 2 (0.7%), PCL rupture 1 (0.35%)	5/216 (2.3%)
Bonutti et al [30]	Retrospective comparison	36	32	0	0
Hass et al [55]	Retrospective cohort	24	391	Deep infection 2 (0.5%), wound drainage 1 (0.25%), skin necrosis 1 (0.25%)	3/391 (0.7%)
Laskin et al [56]	Retrospective cohort	3	32	0	0
		Average: 17.2	Total: 1490	<b>Radiographic complications: 36 (2.4%)</b> Clinical complications: 52 (3.5%) Overall complications: 88 (5.9%)	Overall revisions: 12 (0.8%)

Complication in boldface indicates being radiographic; F/U, follow-up; AVN, avascular necrosis; PCL, posterior cruciate ligament; Abx, antibiotics; RCT, randomized clinical trial; NA, not applicable.



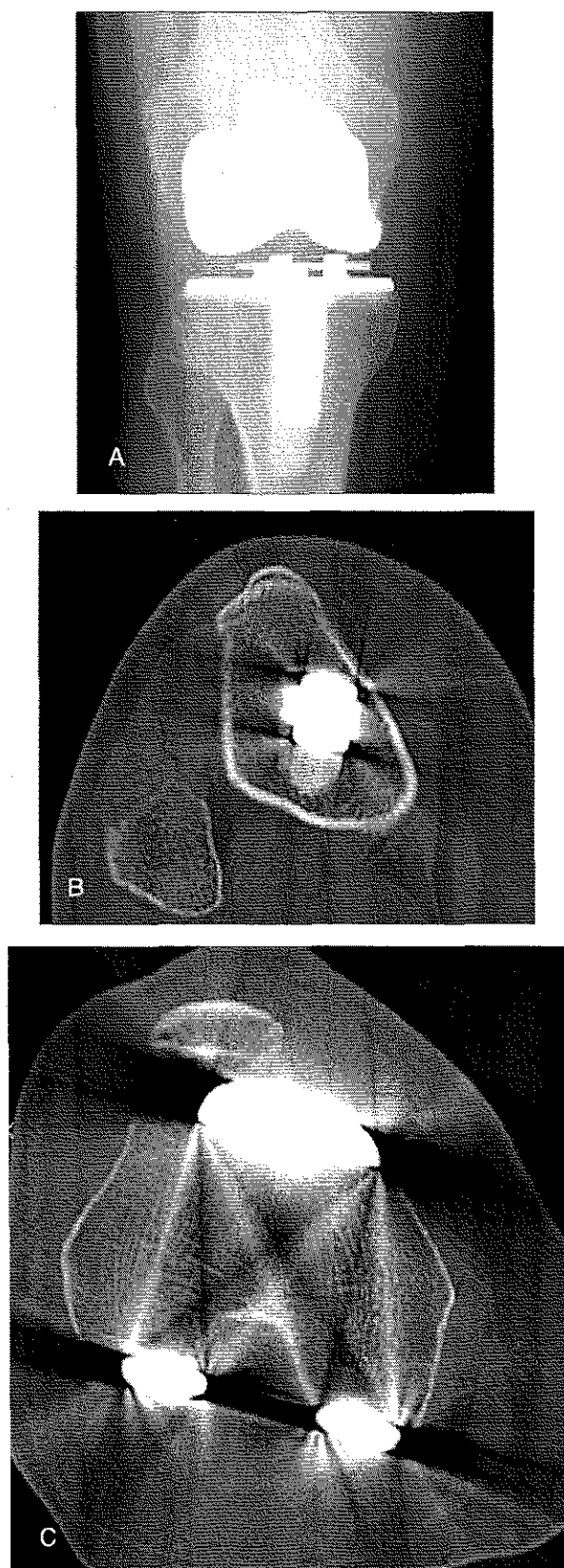
**Fig. 3.** (A), Anteroposterior radiograph of bilateral simultaneous total knees with the right knee demonstrating more tibial varus than that of the left. Right knee was performed with MIS technique and took excessive time (>3 hours). Left knee was performed with a standard approach in less than half the time with substantially less tibial varus. Left knee was symptomatic at 6 months and demonstrated patellar tilt on sunrise view (B) as well as tibial subsidence (C) leading to revision within 1 year.

concern regarding the learning curve for this procedure in the hands of the less experienced.

There are also concerns that the excellent results reported in many recent MIS studies may also be influenced by selection and observer bias. Patients are often selected for MIS based on size, range of motion, activity level, and lack of deformity [38,39]. Highly motivated patients that seek out this procedure and meet these criteria may be prone to a good result regardless of the surgical approach. Most of the early MIS TKA studies also lack a control group of standard TKAs treated with the latest perioperative pain management, rehabilitation, and patient education, which were implemented during the same era as MIS and may account for many of the observed short-term improvements [38,39]. One recent prospective randomized study by Kolisek et al [15] reported no difference in blood loss, operative time, or short-term clinical outcome at 12 weeks. The MIS group did have delayed wound healing in 10% (4/40) compared with 2.5% (1/40) in the standard group. This is the only level I study, to our knowledge, of MIS vs standard TKA with no demonstrable benefit shown for MIS. Another recent study by Pour et al [40] showed that preoperative teaching and conditioning impacted clinical result after joint arthroplasty as much or more than incision size or surgical technique.

Previously published studies of MIS TKA may present the best case scenario of what can be

achieved in selected cases by experienced surgeons. In these series, early failure or revision has been reported in less than 1% of cases. The follow-up of these studies is short, however, averaging only 17 months. There are additional clinical and radiographic complications described in almost 6% of cases, which may lead to a higher midterm failure rate (Table 2). The current series may represent the other end of the spectrum of less experienced lower-volume surgeons who may have been less selective in their indications. This cannot be determined, however, because the clinical status of the patients before the index arthroplasty was not known in the cases in this series. The importance of formal training including cadaver and intraoperative mentorship has been emphasized before embarking on MIS TKA [14,36]. Even with this proviso, experienced surgeons have noted a substantial learning curve [14,17,41]. The extent of training or experience of surgeons performing the original MIS cases in this series is not known, which may be a potential factor in the high number of early failures. The number of early revisions is striking and is more than 3 times the total number of revisions of MIS TKA reported in the English literature to date (Table 2). It should be noted, however, that early revision is not unique to MIS TKA. Fehring et al [42] reported on 440 total knee revisions of non-MIS cases between 1986 and 1999. During this time, 279 (63%) had revisions within 5 years of their index



procedure. Infection was the most common etiology, however, accounting for 38% of cases. Early loosening was rare whether because of failure of ingrowth of a cementless component (8%) and even more rare with a cemented component (3%). Early loosening was much more common in the present series (59% of failures), which would indicate that MIS substantially impaired the ability to reliably ensure adequate fixation in a substantial percentage of these cases (Fig. 2). In another study of revision TKAs by Fehring et al [43], they reported a 20% incidence of instability as the etiology for failure. This is virtually identical to the incidence of instability as a primary etiology of failure for non-MIS cases in the present study but about half the incidence observed in the MIS group, indicating that the limited exposure may well predispose to malalignment, ligament imbalance, and instability (Figs. 1 and 4).

Sharkey et al [44] reported on 212 revision TKAs, more than half of which failed in less than 2 years, so such results are not restricted to MIS knees. They also included infection and rerevisions, however, which undoubtedly shortened their average time to revision. When these groups were excluded in the present study, the average time to revision was almost 7 years, and failure at less than 2 years was relatively rare. A recent study of patient's perspective of revision TKA indicates that satisfaction with the results of TKA declines dramatically when revision is required within 5 years [45].

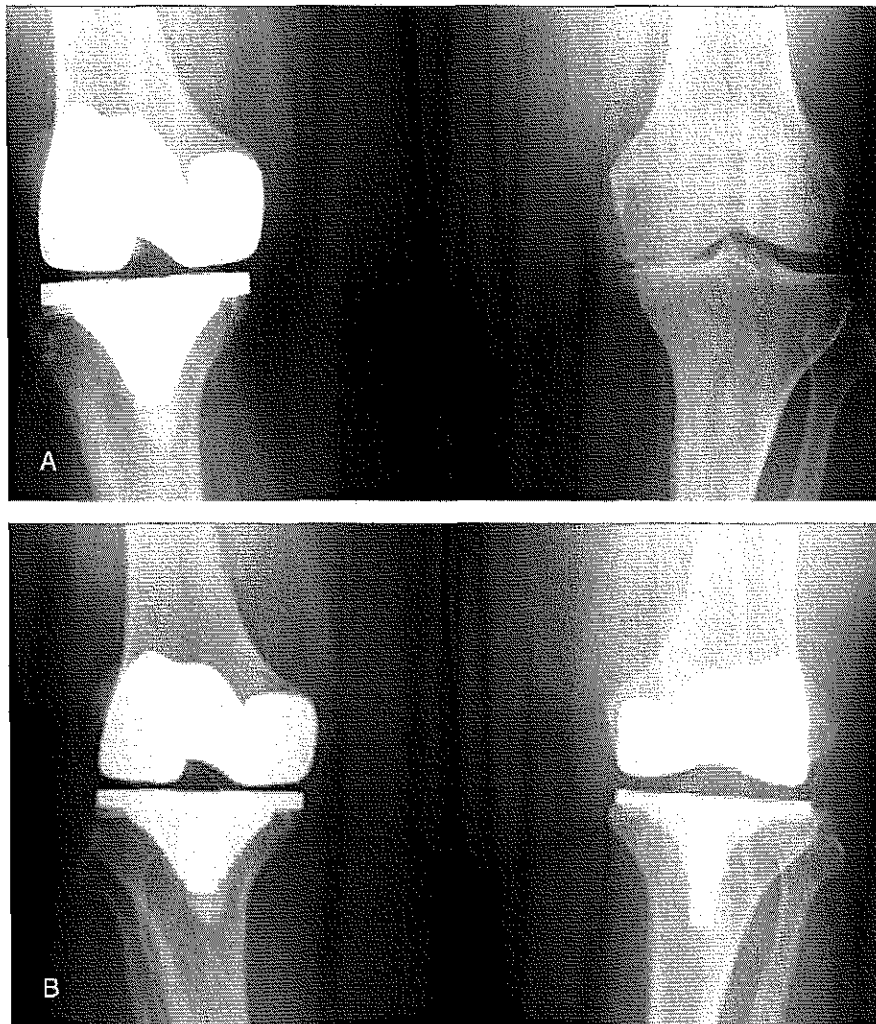
There are weaknesses of the present study. Data on incision length were collected retrospectively, which is less accurate than if all incisions were measured prospectively by the same method. All incisions, however, had a proximal extent within a centimeter of the proximal pole of the patella, and the intent of the surgeon to perform an MIS procedure was reported in the medical records. Data are not available on how many MIS TKAs were performed by surgeons in the referral area of these 3 centers during the period of the study, so the denominator is not known for these 44 early failures. In addition, MIS TKA has only been performed in substantial numbers for approximately 5 years, so the potential for long-term success is limited, which would somewhat bias

**Fig. 4.** Anteroposterior radiograph of MIS TKA suggestive of tibial malrotation based on asymmetry of tibial locking mechanism (A), which was confirmed on computed tomography views showing the stem well medial to the tubercle (B) and subluxation of the patella and femoral internal rotation (C).



the average time to revision in favor of the standard TKAs and also bias the study toward demonstrating more early failures in the MIS group. Nevertheless, failure in less than 2 years should be exceedingly rare. In the 6 most commonly used cemented total knees in the Norwegian Registry before the advent of MIS, the 5-year component survival ranged from 95 to 99 per center [46,47]. It is highly doubtful that a high enough volume of MIS knees was performed in these referral areas to justify the number of early failures observed. Of greater concern is that this small series may represent the tip of the iceberg in 2 considerations. First, if 5 practitioners at 3 centers have encountered more than 40 total knee revisions with a survival time averaging only 15 months, this likely translates into hundreds if not thousands of early failures on a national level,

which is unacceptable and ironic considering this is the result of a technique aimed at improving clinical results. Second, this series of patients only represent the subset of cases in which the symptoms were severe enough to warrant the drastic step of early revision. It is easily possible, if not likely, that there are a far greater number of patients with suboptimal reconstructions who are experiencing compromised clinical results and are at risk for midterm failure from wear or loosening secondary to marginal component fixation or malpositioning (Fig. 5). The percentage of cases failing because of malposition and instability is inflated somewhat because MIS TKA has not been performed long enough to fail from long-term mechanisms such as wear and lysis. Also of concern in this regard is a recent study by Incavo et al [48] indicating that patients who undergo



**Fig. 5.** Young heavy female presented with moderately symptomatic right total knee 1 year after MIS with limited motion (A). After a standard incision of left TKA, she had 120° of motion and no symptoms (B).

early revision for component malposition or instability experience inferior clinical results compared with a primary TKA. In the course of this study, a number of patients who had a marginally functioning MIS knee on one side and elected to have a standard TKA on the other side, resulting in a superior radiographic and clinical result in terms of range of motion and pain relief (Fig. 5), were encountered.

MIS TKA does hold promise of improving the short-term results of TKA. Thus far, the most compelling results have been achieved by high-volume experienced surgeons with a special interest in this technique [10-13,16,19,20,22,30,49,50]. The results of the present study suggest that the results of MIS TKA can be associated with an unacceptably high incidence of complications, including revision. In light of the uniformly excellent long-term results for standard TKA in numerous published studies [3,4,33], it seems prudent to temper the enthusiasm for widespread promotion of MIS TKA until the scope of the problem with suboptimal results, complications, and early revisions can be more clearly elucidated.

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